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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,970	12/03/2004	Jeffrey M. Axten	P51357	3141

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EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/516,970	<b>Applicant(s)</b> AXTEN ET AL.	
	<b>Examiner</b> Laura L. Stockton, Ph.D.	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/3/2004</u> . | 6) <input type="checkbox"/> Other: ____.  |

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**DETAILED ACTION**

**Claim 1 is pending in the application.**

***Information Disclosure Statement***

The Examiner has considered the Information Disclosure Statement filed on December 3, 2004.

***Claim Objections***

Claim 1 is objected to because of the following informalities: a claim must begin with a capital letter. See MPEP 608.01(m).

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

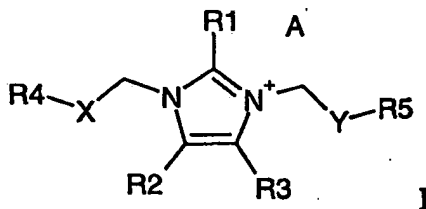
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the counter anion, A<sup>-</sup> is missing in the formula. See formula (I) on page 2, lines 23-24 of the instant specification (also reproduced below).

In a first aspect this invention relates to a compound of formula (I)



wherein:

A<sup>-</sup> is an anion;

R<sub>1</sub>, R<sub>2</sub> and R<sub>3</sub> are the same or different and are hydrogen, C<sub>1</sub>-C<sub>6</sub> alkyl, aryl, fused aryl, or heteroaryl; or are substituted aryl, fused aryl or heteroaryl;

X and Y are the same or different and are -CH<sub>2</sub>, -C=O, -CHOH, -C=S, or -C=NR<sub>6</sub>;

R<sub>4</sub> and R<sub>5</sub> are the same or different and are aryl, substituted aryl, heteroaryl, or substituted heteroaryl; and

R<sub>6</sub> is aryl, C<sub>1</sub>-C<sub>6</sub> alkyl, OH, C<sub>1</sub>-C<sub>6</sub> alkoxy, or aryloxy.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by:

a) CA Registry No. 258264-19-6, entered into the Registry file on STN March 6, 2000;

b) Friary {U.S. Pat. 5,393,753} - see the compound in column 19, lines 22-23 {see CA Registry No. 142654-75-9 in CA 117:90284, 1992};

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c) Chapman et al. {Journal of Heterocyclic Chemistry (Nov-Dec 1990), 27(7), pages 2053-2061} - see, for example, compound 12a {CA Registry No. 134071-10-6} on page 2055;

d) Dominianni et al. {Journal of Medicinal Chemistry, (1989), 32(10), pages 2301-2306} - see compound 60 on page 2305, first column, second full paragraph {CA Registry No. 121704-76-5};

e) Tajana et al. {Bollettino Chimico Farmaceutico (1986), 125(1), pages 7-20} - see, for example, compound XIII {CA Registry No. 104199-91-9} on page 15, first column;

f) Sawa et al. {JP 60-184076} - see the first compound on page 4 in column 1 {CA Registry No. 102570-31-0};

g) Tajana et al. {Arzneimittel-Forschung (1981), 31(12), pages 2127-2133} - see compound 11 at the bottom of page 2127 {CA Registry No. 80639-90-3 or Beilstein Records (BRN) 6559619};

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h) Tajana et al. {Arzneimittel-Forschung (1981), 31(12), pages 2121-2123} - see 1,3-bis-p-phenylthiophenacyl-2-methylimidazolium bromide {CA Registry No. 80624-62-0 or Beilstein Records (BRN) 6560594} on page 2122, first column last line before Table 1;

i) Cappelletti et al. {Bollettino Chimico Farmaceutico (1981), 120(7), pages 383-391} - see, for example, the first compound {CA Registry No. 80591-05-5} in Table II on page 388;

j) Tajana et al. {Bollettino Chimico Farmaceutico (1981), 120(3), pages 185-190} - see, for example, compound 3a {CA Registry No. 78886-55-2} in Table II on page 187;

k) Nardi et al. {Journal of Medicinal Chemistry (1981), 24(6), pages 727-731} - see, for example, the first compound in Table II at the bottom of page 728 {CA Registry No. 77234-62-9};

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l) Kochergin et al. {CA 85:62993, 1976} - see the compound of CA Registry No. 60053-03-4;

m) Jones et al. {Canadian Journal of Chemistry (1971), 49(2), pages 325-332} - see compound 13d {CA Registry No. 31410-05-6} on page 327;

n) Salero et al. {Pharmazie, 54(9), 1999, pages 685-690} - see, for example, 1,3-bis(phenacyl)-imidazolium bromide on page 689, first column, under "3.1. Chemistry";

o) Leonardi et al. {Farmaco Ed. Sci., 36(8), 1981, pages 711-720} - see the compound on the fifth line {Beilstein Records (BRN) 6764083} under Method E on page 718;

p) Porretta et al. {Eur. J. Med. Chem. Chim. Ther., 28(10), 1993, pages 749-760} - see, for example, compound 4b in Table I on page 750 and the last sentence on page 756 {Beilstein Records (BRN) 6627407};

or



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q) Stolz et al. {DE 488,681} - see, for example, the compound on page 3, lines 11-12 {Beilstein Records (BRN) 3844543}.

Each of the above cited prior art disclose at least one compound that is embraced by the instant claimed invention. Therefore, the instant claimed invention is anticipated by each of the above cited prior art.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Ulrich et al. {U.S. Pat. 6,777,557}.

Ulrich et al. disclose, for example, the compound in column 16, line 18 {see CA Registry No. 31410-05-6 in CA 137:169535, 2002} which is embraced by the instant claimed invention.

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 1 rejected under 35 U.S.C. 103(a) as being unpatentable over Ulrich et al. {U.S. Pat. 6,777,557} and Diamond et al. {U.S. Pat. 4,613,609}, each taken alone.

***Determination of the scope and content of the prior art (MPEP §2141.01)***

Applicants claim an imidazolium compound. Ulrich et al. (column 5, lines 19-37; and especially the compounds in column 16, lines 18-30 and 57-64) and Diamond et al. (columns 1-2; and especially compound 24 in column 3, lines 54-55) each teach an imidazolium compound that is either structurally the same as (see

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above 102 rejection) or structurally similar to the instant claimed compounds.

*Ascertainment of the difference between the prior art and the claims*

*(MPEP §2141.02)*

The difference between some of the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in each of the prior art references.

*Finding of prima facie obviousness--rational and motivation (MPEP*

*§2142-2413)*

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e., treating diabetes).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at

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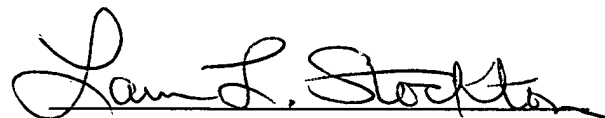
the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, diabetes. The instant claimed invention would have been suggested and therefore, obvious to one skilled in the art. A strong case of *prima facie* obviousness has been established.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in black ink, reading "Laura L. Stockton". The signature is fluid and cursive, with the first name "Laura" and last name "Stockton" clearly distinguishable.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

December 1, 2005